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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/351,778	07/12/1999	WILLIAM S. M. WOLD	16153-7775	1203

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EXAMINER

WEHBE, ANNE MARIE SABRINA

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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08/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 09/351,778	Applicant(s) WOLD ET AL.	
	Examiner Anne Marie S. Wehbe	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-9, 11-44, 60-84 and 97-108 is/are pending in the application.
- 4a) Of the above claim(s) 6-9 and 25-27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5, 11-17, 20-24, 32-44, 60-62, 64-75, 78, 79, 97-100 and 103-108 is/are allowed.
- 6) ☒ Claim(s) 18, 19, 28-31, 76, 77, 80-84, 101-102 is/are rejected.
- 7) ☒ Claim(s) 63 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Please note that the examiner of record and art unit of record for this application have changed. See concluding paragraph for detailed contact information.

Status of the Claims

A second decision on appeal under 35 USC 134 from the Board of Patent Appeals and Interferences (BPAI) was mailed to applicants on 4/17/08.

Claims 5-9, 11-44, 60-84, and 97-108 are pending in the instant application, based on the last claim amendment filed by applicants on 12/8/03. The status of these claims is set forth below based on the first BPAI decision on appeal mailed to applicant's on 1/26/06, the Decision of the BPAI on applicant's request for rehearing mailed on 9/28/06, and the second BPAI decision on appeal mailed on 4/17/08.

Claims 6-9, 16-19, 23, 25-31, and 76-84 have been withdrawn from prosecution by previous examiners in view of applicant's election without traverse of the subject matter of Group I in the response received on 10/10/00. Prosecution is closed in regards to withdrawn claims 6-9, which were originally identified as part of Groups II or III and which depend on canceled claim 3, and claims 25-27 which were originally identified as part of Groups IV, V, or VI. Claims 6-9 and 25-27 will be subject to cancellation by the examiner upon allowance of the instant application, see MPEP 1214.06. Claims 16-19, 23, 28-31, and 76-84 have been identified by the current examiner as eligible for rejoinder based on their dependence on linking claims 13

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or 60, now allowed, see below and the section entitled *Rejoinder of certain withdrawn claims* for more details.

Claim 5 was indicated as allowable in the final office action mailed on 2/19/04.

Claims 11-15, 20-22, 24, 32-44, 60-75, and 97-108 were under appeal to the BPAI which rendered the following decisions based on rejections of the claims under 35 USC 112, first paragraph, 35 USC 112, second paragraph, 35 USC 102, and 35 USC 103:

1) the rejection of claims 11-15, 20-22, 24, 33-44, 60-75, 97-103, and 107-108 under 35 U.S.C. 112, first paragraph for lack of written description was **reversed** by the first BPAI decision of 1/26/06.

2) the rejection of claims 32 and 104-106 under 35 U.S.C. 112, first paragraph for lack of written description was affirmed by the first BPAI decision of 1/26/06 and later **reversed** in the Decision on applicants request for rehearing mailed on 9/28/06.

3) the rejection of claims 101-102 under 35 U.S.C. 112, second paragraph, for indefiniteness was **affirmed** by the first BPAI decision of 1/26/06. The applicant did not request rehearing of this rejection in the request filed on 3/28/06 (note that a duplicate of the request was also filed on 5/3/06).

4) the rejections of claims 11-13, 32-44, 60-61, 68-69, 72-75, 97-99, and 101-108 under 35 U.S.C. 102(e) over Henderson (US 6,197,293 B1, Mar. 6, 2001) or Little (US 6,254,862 B1, Jul. 3, 2001), and the rejection claims 13, 20-22, 60, and 64-66 under 35 U.S.C. 103(a) over Henderson or Little in view of Freytag et al. were affirmed in the first BPAI decision of 1/26/06, subject to remand to the previous examiner as a result of the Decision on applicants request for rehearing mailed on 9/28/06, and subsequently **reversed** in the second BPAI decision of 4/17/08.

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As a result of the above decisions, claims 5, 11-15, 20-22, 24, 32-44, 60-62, 64-75, 97-100, and 103-108 are considered allowed and prosecution is closed. Due to the allowance of claim 15, claim 63 as been objected to under 37 CFR 1.75, see below. Prosecution is also closed for claims 101-102, the rejection of which under 112, second, was affirmed by the BPAI. Claims 101-102 will be subject to cancellation by the examiner upon allowance of the instant application, see MPEP 1214.06.

Rejoinder of Certain Withdrawn Claims

Claims 16-19, 23, 28-31, and 76-84 depend directly or indirectly on either independent claim 13 or 60. As an initial matter, the instant examiner finds that claim 23 was mistakenly included in Groups IV-VI, whereas it should have been included in group I and examined along with the originally elected subject matter. Claim 23 is therefore rejoined. Further, as noted above, previous rejections over claims 13 and 60 have been reversed by the BPAI. Claims 13 and 60 are therefore considered allowed. While the original restriction requirement prepared by a previous examiner and mailed on 9/7/00 did not identify claim 13 as a linking claim, this claim were included in all of Groups I-III. Further, in the office action mailed on 9/3/03, a different previous examiner identified claim 13 and claim 60, added by amendment, as linking claims for inventions I-III and indicated that upon allowance of the linking claims, the restriction requirement would be withdrawn and that claims depending from the allowed linking claims would be entitled to examination. As claims 13 and 60 have been allowed, dependent claims 16-19, 23, 28-31, and 76-84 are hereby rejoined and limited prosecution resumes confined solely to

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the determination of the patentability of dependent claims 16-19, 23, 28-31, and 76-84, see MPEP 1214.06, section III.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-19, 28-31, 76-77, and 80-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 recites the limitation "the recombinant adenovirus" in line 1. There is insufficient antecedent basis for this limitation in the claim or in parent claims 12 or 13.

Claim 18 is further indefinite in that it recites in the alternative that the adenovirus comprises a tissue specific promoter or an inducible promoter substituted for the E4 promoter. Claim 18 depends on claim 12 which depends on independent claim 13. Claim 13 contains the limitation of administering an adenovirus vector which is replication-competent in neoplastic cells to a tumor in an animal. E4 is an adenovirus protein essential for replication. However, the limitation in claim 18 that the E4 promoter is exchanged for a tissue-specific promoter or inducible promoter conflicts in part with the limitation of claim 13. The term tissue-specific promoter is not limited to tumor tissue and thus encompasses the use of numerous tissue-specific promoters which would not drive transcription in tumor cells. As such, the breadth of adenovirus recited in claim 18 conflicts with the breadth of the adenovirus vector recited in the parent claim which requires replication competency in neoplastic cells. In regards to the alternative

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embodiment of using an inducible promoter, an adenovirus vector comprising such an inducible promoter substituted for the E4 promoter would only be replication competent in the presence of the inducer. However, the claim lacks the essential step of administering the inducer to achieve replication competency. Claim 19 depends on claim 18 and thus is included in this rejection.

Claim 19 is further confusing in the recitation of "wherein the recombinant adenovirus which comprises SEQ ID NO:14, SEDQ ID NO:15, or SEQ ID NO:16." The inclusion of the word "which" renders the claim unclear and appears to be a typographical error. The examiner suggests deleting the word "which".

Claim 28 is indefinite in that it depends on claim 13 and contains limitations which conflict with the limitations of the parent claim. Claim 13 contains the limitation of administering an adenovirus vector which is replication-competent in neoplastic cells to a tumor in an animal. Claim 28 recite that "the adenovirus vector is replication defective, or it is replication-restricted to dividing cells or neoplastic cells". As claim 13 requires the vector to be replication competent, the limitation in claim 28 that the vector is replication defective is confusing and appears to conflict with the limitations of claim 13. As indicated by a previous examiner, the specification defines "replication defective" virus vectors as incapable of replicating their genome in any cell type in the absence of a replication-competent virus, see page 11 of the specification. Therefore, the conflicting limitation in claim 28 renders the claim indefinite. Note that the alternative embodiment where the vector is identified as being replication-restricted to dividing cells or neoplastic cells is not considered indefinite. Claims 29-31 depend on claim 28 and thus are included in this rejection. It is suggested that the applicant

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delete the embodiment of a replication-defective vector in claim 28 to overcome the rejection of claims 28-31.

Claim 76 is indefinite in that it depends on claim 60 and contains limitations which conflict with the limitations of the parent claim. Claim 60 contains the limitation of administering an adenovirus vector which is replication-competent in neoplastic cells to a tumor in an animal. Claim 76 recites that "the adenovirus vector is replication defective". As claim 60 requires the vector to be replication competent, the limitation in claim 76 that the vector is replication defective is confusing and appears to conflict with the limitations of claim 60. As indicated by a previous examiner, the specification defines "replication defective" virus vectors as incapable of replicating their genome in any cell type in the absence of a replication-competent virus, see page 11 of the specification. Therefore, the conflicting limitation in claim 76 renders the claim indefinite such that the metes and bounds cannot be determined. Claim 77 depends on claim 76 and thus is included in this rejection. However, it is further noted that as the vector in claim 76 is "replication-defective", the limitation in claim 77 that the vector is replication-restricted to neoplastic cells further confuses the claimed invention. It is suggested that claim 77 be amended to depend on claim 60 rather than claim 76.

Claims 80-82 are indefinite in the recitation that the vector comprises an adenoviral gene essential for replication, or specifically the E4 gene, under the control of a tissue specific promoter. Claim 82 further recites that the promoter is "a transcriptional regulatory element" or a number of specific promoter species. Claims 80-82 depend directly or indirectly on claim 60. Claim 60 contains the limitation of administering an adenovirus vector which is replication-competent in neoplastic cells to a tumor in an animal. E4 is an adenovirus protein essential for

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replication. However, the limitation in claims 80-82 that the E4 promoter is exchanged for a tissue-specific promoter conflicts in part with the limitation of claim 60. The term tissue-specific promoter is not limited to tumor tissue and thus encompasses the use of numerous tissue-specific promoters which would not drive transcription in tumor cells. Further, the recitation of the genus of "transcriptional regulatory elements" in claim 82 encompasses any sequence capable of modifying transcription, not limited to any particular tissue or cell type, including a neoplastic cell type. As such, the breadth of adenovirus recited in claims 80-82 conflicts with the breadth of the adenovirus vector recited in the parent claim which requires replication competency in neoplastic cells.

Claims 83-84 are indefinite in the recitation that the vector comprises an adenoviral gene essential for replication under control of an inducible promoter. Claims 83-84 depend directly or indirectly on claim 60, which recites the method step of administering an adenovirus vector which is replication-competent in neoplastic cells to a tumor in an animal. An adenovirus vector comprising an inducible promoter operably linked to a gene essential for replication would only be replication competent in the presence of the inducer. However, claims 60 and 83-84 lack the essential step of administering the inducer to achieve replication competency. In the absence of an inducer, the vector comprising such an inducible promoter operably linked to a gene essential for replication would not be replication competent in neoplastic cells and thus would be in conflict with the method of claim 60.

Claim Objections

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Claim 63 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 15. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). It is noted that the applicant was warned in the office action mailed on 9/3/03 that should claim 15 be found allowable, claim 63 would be objected to for claiming duplicate subject matter.

Conclusion

Claims 5, 11-15, 20-22, 24, 32-44, 60-62, 64-75, 97-100, and 103-108 are allowed, prosecution is closed.

Claim 63 is objected to as being a substantial duplicate of claim 15.

Claims 101-102, rejection under 112, second affirmed, prosecution is closed and claims subject to cancellation by examiner upon allowance of application.

Claims 6-9 and 25-27 remain withdrawn from prosecution as being drawn to an invention non-elected without traverse. Prosecution is closed and the claims are subject to cancellation by examiner upon allowance of application.

Claims 16-17, 23, 78-79 are rejoined and considered allowable.

Claims 18-19, 28-31, 76-77, and 80-84 are rejoined and stand rejected under 35 U.S.C. 112, second paragraph.

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Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197.

Representatives are available daily from 6am to midnight (EST). When calling please have your application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

/Anne Marie S. Wehbé/

Primary Examiner, A.U. 1633